must be sent in writing. Either the carrier or entity may appeal the hearings officer's decision to CMS.

(d) A CMS official, designated by the Administrator of CMS, must make an appeal decision based on the evidence presented to the fair hearing officer and his or her decision. The CMS official requests any additional information he or she deems necessary from either the carrier or the entity within two weeks of receipt by the CMS of the appeal. Notice of the CMS official's decision—

(1) Is issued within two weeks of when the last information is received is received by the CMS official, or four weeks of when the information is requested, whichever is shorter, unless the party appealing the fair hearing decision requests a delay;

(2) Is sent by the CMS official by certified mail to both the carrier and the entity; and

(3) Contains information on any further appeals the entity and carrier may have.

(e) A billing number is not issued, or remains revoked, and payment is not made, for items or services furnished by any entity which a carrier determines does not qualify for a billing number, until the carrier (upon reapplication of the entity), a fair hearing officer, or a CMS official designated to hear such appeals, determines that the entity qualifies for a billing number. Any claims for items or services furnished after revocation of the supplier's billing number and submitted by the entity during the appeals period are held and not processed, i.e., are neither approved, denied or developed, until all administrative appeals have been exhausted. If an entity is determined not to have qualified for a billing number in one period but to have qualified in another, the carrier pays for claims for items sold or rented to beneficiaries during the period the entity qualified as a supplier. If there is evidence of an overpayment, see subpart C of part 405 of this Chapter.

(f) A billing number may be reinstated after revocation when an entity completes a corrective action plan, to which CMS has agreed, and provided sufficient assurance of its intent to comply fully with the supplier standards.

[57 FR 27305, June 18, 1992]

§ 405.877 Appeal of a categorization of a device.

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the provisions of sections 1869 (a) through (e) and (g) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under